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Teva Pharmaceutical Industries Ltd.

(TEVA)

Q1 2022 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Good day, and thank you for standing by, and welcome to Teva's First Quarter 2022 Financial Results Conference Call. At this time, all participants are in a listen-only mode. After the speaker presentations, there will be a question-answer session. [Operator Instructions] Please be advised that today's conference is being recorded. [Operator Instructions]

I would now like to hand the conference over to your first speaker today, Ran Meir, Senior Vice President, Investor Relations. Please go ahead, sir.

Ran Meir
Senior Vice President-Investor Relations & Corporate Communications, Teva Pharmaceutical Industries Ltd.

Thank you, Annette. Thank you, everyone, for joining us today to discuss Teva's first quarter 2022 financial results. We hope you have had an opportunity to review our earnings press release, which was issued earlier this morning. A copy of this press release as well as a copy of the slides being presented on this call can be found on our website at tevapharm.com.

Please review our forward-looking statements on slide number 2. Additional information regarding these statements and our non-GAAP financial measures is available on our earnings release and in our SEC forms, 10-K and 10-Q.

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To begin today's call, Kåre Schultz, Teva's CEO, will provide an overview of the first quarter performance, recent events and priorities going forward. Our CFO, Eli Kalif, will follow up by reviewing the financial results in more detail, including our 2022 financial outlook. Joining Kåre and Eli on the call today is Sven Dethlefs, Teva's Head of North America Commercial, who will be available during the question-and-answer session that will follow the presentation. Please note that today's call will run approximately one hour.

And with that, I will now turn the call over to Kåre. Kåre, if you would, please.

Kåre Schultz

President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

Thank you. Welcome, everyone. I'm happy to present a solid first quarter of this year, with continued progress on many fronts. If we take a look at the financials, then revenues came in at $3.7 billion, our adjusted EBITDA came in at $1.1 billion, and our GAAP diluted loss per share was $0.86 and our non-GAAP diluted EPS came in at $0.55. The free cash flow came in at $117 million, and we're happy to show you that the debt reduction continued and net debt is now reduced to $20.7 billion. Our 2022 revenue outlook has been revised slightly downward mainly due to foreign exchange headwinds. All the other key components, as we will show you later, are being reaffirmed.

On the business side, we were very happy to see continued growth of AUSTEDO prescriptions, growing to a new all-time high. And at the same time, we also saw a growth in market share for our other key growth driver AJOVY, where we saw a strong development in Europe and also nice progress in the US.

In Europe, our generics and OTC markets were recovering following the easing of COVID-19 restrictions. So, we saw a comeback of volumes and a nice continued strong market position in all key markets. In North America generics, we were very happy to launch the new generic REVLIMID, which did very well, and that was partly compensating for the lack of TRUVADA and Atripla sales that we had last year and also a decline in ProAir sales. Our biosimilar pipeline is progressing very nicely. We're excited about biosimilar HUMIRA, which we now have a settled entry date of July 2023 for next year and, of course, we have there a pending FDA approval.

If we move to the next slide, then you can see a highlight on the opioid litigation. As you all know, we have settled in Rhode Island in March and we also settled in Florida in March. And then we have, based on this, also changed our accrual on the balance sheet, and Eli Kalif will comment a bit on that later.

There are two ongoing trials right now, one in West Virginia and one in San Francisco, both are bench trials, which means there is a judge presiding over it, there's no jury. Our experience with bench trials recently has been positive. We had the trial in California, in Orange County, where we won a clear victory, and there was also J&J that appealed to the Oklahoma Supreme Court, which was also a bench trial, where there was also a win. We are in ongoing negotiations, and we are hopeful that we can settle this with a nationwide settlement for all states sometime before the end of this year.

If we go to the next slide, and here you can see our revenue development. And you can see that in the first quarter, we had two, you could say, negative developments compared to the first quarter of 2021. One was that the exchange rate between Europe and US between the euro and the dollar worsened, so there was a significant increase in the dollar value in euros. And that basically meant that the reported euro – sales in dollars is down. In underlying currencies, the sales are actually up. And we see, as I said before, a positive development of volumes in the generic space in Europe.

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In the US, the key difference here is really, like I mentioned before, that we had TRUVADA and Atripla sales in the first quarter of 2021, and we have had REVLIMID sales in first quarter 2022, but not to the same extent. And in international markets, you see a very stable development.

If we go to the next slide, then here, as I comment on AUSTEDO, you can see that we have an all-time high TRx count in the end of the first quarter. If you look at the revenues, then we had the usual swing there where the first quarter is always low and there are really two main reasons for it. One is the spec buying that we see in the fourth quarter due to the fact that we traditionally now take our price increases in the very first week of the year.

And the other one is the fact that the donut hole effects reset of patient deductible programs and, therefore, we see less demand in the first quarter. We expect the demand, of course, to swing back up as this has done all years based on the prescriptions, and we are still maintaining the outlook for AUSTEDO for the year of $1 billion in sales.

If we go to the next slide, then here you can see AJOVY. And in the US, you can see that we also there have an all-time high of the TRx-es. And you can also see that in Europe, we have an all-time high of the monthly volume market share, which is now up to 30%. I've said before that we are expecting to see a third of the market in all key markets, including Europe and US. So, we are really aiming for at least a 33% market share in both North America and Europe, and we are slowly getting there, which is very, very nice.

You can also see here on the sales numbers that the sales in Europe are now getting up and being close to the US sales, and we expect that to continue going forward. So, we see very positive both profitability and momentum in Europe.

If you go to the next slide, then we have the news here that we communicated some weeks ago that we received a CRL on risperidone LAI. So, we will be answering the questions that we got from FDA. We expect that this could cause a delay of a re-filing with some up to six months and then probably a six-month review period. We still have strong belief in the concept and in the efficacy. So, we still believe to get this product approved, but there will likely be a delay of up to 12 months on it.

Another thing you can see here is illustrated on the next slide, and that's the fact that we have a very broad biosimilar portfolio. We have 13 biosimilars in development now, 7 in-house programs and 6 that we have from partners. And of course, we are very excited about the big launch that's upcoming next year, the HUMIRA launch. We now have a settled entry date of July 2023. And as you know, this is a very good product. It's the high concentration version, citrate-free and interchangeable. So, we are looking forward to that.

We think we are still seeing very good performance on the ones we have launched. So, TRUXIMA is doing exceedingly well in the marketplace still holding onto something like a quarter of the RITUXAN market. And we're also happy now that this year we will see a launch in Europe of a LUCENTIS biosimilar. So, all in all, it's going very well on the biosimilar side. And longer term, of course, we are aiming for addressing some roughly 80% of the value in biologic products going off patent, both in North America and in Europe.

On the next slide, you see another important element of our restructuring, which is basically, you could say, post the patent cliff of COPAXONE to get our operating margin back up where it should be. And as you know, back in 2018, we set a target of 28%. And you can see here now that we're getting very close. And just for the record, I would like to say, even though the graph could look like it's flattening out, then, of course, we're not going to stop at 28%. We will set new long-term targets, which will be an improvement and we will communicate those targets within the coming year.

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The same goes for the next slide where we have another of our key financial targets shown, that's the net debt reduction. As you know, we have a target to reduce net debt. And also there, we'll keep on driving it down. And the same goes for the net debt-to-EBITDA ratio. We will be setting a new target for that. We have a target for end of 2023, below 3 times, and we'll be setting a new long-term financial target also for the net debt-to-EBITDA within the coming year.

On the next page, you can see we're making a little commercial for our upcoming ESG Progress Report, which will come out in about a week's time. And we've been working very hard on this for a number of years, and we are setting some very ambitious targets. We're also making sure that our ESG performance is linked to executive compensation. We also have secured now that our – you could say, our financing, our debt is linked to sustainability. Eli Kalif will tell you later on about our new RCF, which also has a sustainability element.

And all through, we are very happy about our performance. And we're also happy that it's been seen outside the company. So, we see improved performance on our ESG ratings, which, of course, is a good sign that we are doing the right thing.

If we go to the next slide, then that's a slide that those of you who follow the company, you've seen it many times. We've shown it since 2018. It's our long-term financial targets. There's no change here. And the only change is sort of a little commercial here also that within the coming year, we will come up with new long-term financial targets taking us into the next five-year period. I look forward to that, of course, and I also look forward to meeting these targets at the end of 2023.

So, with that, I will hand you over to Eli Kalif.

Eli Kalif

Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.

Thank you, Kåre, and good morning and good afternoon to everyone. I'll begin my review of the first quarter of 2022 financial results on slide 16, starting with our GAAP performance.

Revenues in the first quarter of 2022 were $3.7 billion, a decrease of 8%, or 5% in local currency terms, compared to the first quarter of 2021. This decrease was mainly due to lower revenues in our North America segment, mainly driven by generics products and COPAXONE, partially offset by higher revenue from Anda and generic products in our Europe segment. We have been seeing generic product launches for Teva towards the end of the first quarter. However, the decrease in our revenues from generic products in North America is still affected by the low number of launches in 2021.

In Q1 2022, we recorded a GAAP operating loss of $713 million, compared to operating income of $434 million in Q1 2021; GAAP net loss of $955 million compared to a net income of $77 million in Q1 2021; a GAAP loss per share of $0.86 compared to earning per share of $0.07 in the same period a year ago. GAAP operating loss, net loss and loss per share were mainly driven by higher legal settlement expenses related to an update of the estimated settlement provision recorded in connection with the remaining opioid cases in the first quarter of 2022.

Foreign exchange rate movements during the first quarter of 2022, including hedging effects, negatively impacted revenue and GAAP operating income by $133 million and $56 million, respectively, compared to the first quarter of 2021. This was a result of impact of the stronger US dollar, especially versus the euro. As a reminder, approximately 50% of our revenues come from sales denominated in non-US dollar currency.

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Turning to slide 17, you can see that the net non-GAAP adjustment in the first quarter of 2022 were $1.564 billion versus $621 million in Q1 2021. Non-GAAP operating income, net income and earning per share for the first quarter of 2022 were adjusted to exclude these items. Notable non-GAAP adjustment include legal settlement of $1.124 billion, mainly due to an update of the estimated opioid settlement provision mentioned above. Amortization of purchased intangible assets totaling $200 million, the majority of which is included in cost of goods sold and impairment of long-lived assets totaling $165 million.

Moving to slide 18 for a review of our non-GAAP performance. I've already discussed our first quarter revenues, which totaled approximately $3.7 billion. Now, let's move down to the P&L and look on the margins. Despite a 7% quarter-over-quarter decline in non-GAAP gross profit, our total non-GAAP gross profit margin improved to 54.2% compared to 53.8% in Q1 2021. The increase in non-GAAP gross profit margin was mainly driven by our continuous efforts to improve our cost of goods sold, network consolidation activities as well as a change in product portfolio mix in our international market segments, partially offset by unfavorable mix of generic products in our North America segment and lower revenues from COPAXONE.

Our non-GAAP operating margin was 27.7% versus 27.1% in Q1 2021. This increase was driven mainly by higher gross profit margin mentioned above and lower operating expenses, which I will discuss in the next slide. We ended the quarter with a non-GAAP earning per share of $0.55, compared to $0.63 in Q1 2021, mostly due to lower revenue, which were negatively impacted by $133 million from exchange rate fluctuation.

Turning to slide 19. We see that our quarterly spend base declined by $257 million, or $183 million net of FX. Most of the decrease was due to a lower cost of goods sold, partially related to lower sales as well to our ongoing efforts to transform our global operational network. Lower operating expenses also contributed to the decline in our spend base, mainly due to the ongoing active management of such expenses.

We expected the overall annual spend base to remain below $12 billion, as we continue to focus our efforts on reducing and optimizing our cost of goods sold. These ongoing efforts are expected to help us partially mitigate the global macroeconomic headwinds, including inflation and higher cost of labor and eventually lead to stabilize our operating margin above the level of 27% in 2022, with the ultimate goal of 28% operating margin by end of 2023.

Turning to free cash flow on slide 20. Our free cash flow in the first quarter of 2022 was $117 million. Teva free cash flow tends to face headwinds at the start of the year due to unusual timing of annual bonus payments out of this first quarter. In addition, we faced challenges due to timing of certain items related to our working capital as a result of operational ramp-ups in relation to our annual production plan.

Today, we are reaffirming our 2022 free cash flow guidance, which we provided in February. Our 2022 free cash flow is expected to be in the range of $1.9 billion to $2.2 billion. We expect our free cash flow to pick up during the next three quarters, as we continue to drive working capital improvements. We remain on track to achieve our objective of 80% or greater free cash flow conversion by the end of 2023 as part of our long-term financial target.

Turning to slide 21. Our net debt at the end of Q1 2022 was $20.7 billion, compared to $20.9 billion at the end of 2021. The decrease in our gross net debt was mainly due to exchange rate fluctuation. Our net debt-to-EBITDA slightly increased, coming in 4.29 ratio times of Q1 2022. However, we expect it to further decline as we continue to make progress towards our 2023 target of being below 3 times by the end of that year. Debt reduction continues to be our primary focus and main use of cash. Upcoming maturities include $1.4 billion in 2022, which will be covered by our liquidity and expected cash flow generation.

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I would like to inform you that we recently entered into an unsecured syndicated sustainability-linked revolving credit facility of $1.8 billion, replacing our existing facility. It is linked to sustainable performance targets and reinforce our continued intention to establish a direct link between our corporate responsibility commitments and our funding strategy.

So, now turning to our non-GAAP financial outlook for 2022 on slide 22. While we have experienced some recovery in many countries and products from effect of the global pandemic, we are unfortunately also seeing a strong foreign exchange headwind affect our results. At current rates, we expect foreign exchange to have unfavorable impact on revenue.

Therefore, we believe, at this time, it is prudent to adjust our guidance range for full year revenue from the original range of $15.6 billion to $16.2 billion to the new range of $15.4 billion to $16 billion. This lowers the midpoint of our range by $200 million. The new range includes an adjustment to our full year expectation for global sales of COPAXONE for which we are lowering our guidance by $100 million to $750 million due to increase in generic competition in the United States and the availability of alternative therapies as well as continued effect of foreign exchange fluctuation.

For our 2022 financials, operating income, EBITDA, earning per share and free cash flow, we are reaffirming the range provided in February. We expect a gradual pickup in the second quarter following the first quarter, which is expected to be the lowest of our four quarters for sales and margins. We still expect that approximately 45% of our 2022 sales will be generated in the first half of the year and approximately 55% in the second half. As discussed earlier, we also still expect continued impact of foreign exchange fluctuations on our results.

This concludes my review of Teva results for the first quarter of 2022. We'll now open the call for questions and answers. Operator, would you please open the call for questions?

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QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] And the first question comes from the line of Bajal Parsa (sic) [Balaji Prasad] from Barclays. Please ask your question. Your line is now open.

Balaji Prasad
Analyst, Barclays Capital, Inc.

Q

Hi. Good morning and thanks for taking the question. This is Balaji from Barclays. Firstly, on global opioid settlement, Kåre, I couldn't help notice that you seem to call out a more specific timeline this time around for the first time, stating that you expect to see a settlement by the end of the year. So, could you give some incremental color around the progress that you're seeing at least to the extent that is disclosable? And what role will the state settlements play as you go towards this date?

And secondly, on biosimilar HUMIRA, can you give your thoughts on the relevance of the high concentration, interchangeability and the impact on share dynamics that you expect with or without this interchangeability? Thank you.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Thank you, Balaji. I didn't – there was a small thing on your opioid question, where the sound just dropped out. So, I got it that you wanted some more color on it, but there was some specific element you asked about, which I couldn't hear.

Balaji Prasad
Analyst, Barclays Capital, Inc.

Q

Yeah. Yeah. You seem to have been mentioning a more specific timeline for the first time, stating that you expect some progress by the end of the year. So, was asking what progress and what color you could provide further on it. Thank you.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Okay. Thank you very much. So, I'll take the first question, and then Sven can comment on HUMIRA in the US and those elements. So, on the opioids, you can see that we have been doing a number of settlements on a state-by-state basis so far and you can see that there are some common elements there in all the settlements, which, you could say, two main elements. One is, it's a combination of product that can benefit people suffering from substance abuse. So, we have products in there. And you can also see that we are paying over a longer period of time.

And of course, the reason why we need to pay over a longer period of time is due to our balance sheet and the debt we just talked about. So, the only way it's possible for us to do it is if we spread out the payments. And the other thing is, of course, we can bring value to the table due to the fact that we are one of the biggest manufacturers of generics in the world, if not the biggest, and also in North America, we have generic Narcan, which can be used to help people if they overdose.

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So, we're very happy about those settlements. And in conjunction with that, we, of course, also have ongoing negotiations on a nationwide settlement, and we also believe we're getting closer there. So, I'm slightly more optimistic on the time schedule now, and that's why I hope that we will see a nationwide settlement before the end of this year.

Sven, will you address the biosims HUMIRA question?

Sven Dethlefs A
Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.

Yes. Thank you, Balaji. So, on the biosimilars for HUMIRA, we have now a clear situation due to the settlement between Alvotech and AbbVie concerning the launch of this product. So, we will be in the second wave in July 2023 with our product formulation. The product features themselves, I would say, every single feature in itself is, of course, not a decisive factor, but it is the whole package of our product that makes it attractive.

So, it's citrate-free, it's interchangeable and it's high concentration and it also has an attractive auto-injector. And what we know with the payer discussions is that payers very well, of course, analyze the features of each product offering coming to the market in July next year and we believe that the total package that we offer is highly attractive to provide us market access. That is one aspect of the product features.

The second one is, of course, to create pull-through in the market once you have the product in the market, because this product launch will behave not like a classical generic launch in the US, but it has more features of a European branded generic launch. And there we know that the product features and the attractiveness of the package is quite important. So, we are quite happy with the Alvotech HUMIRA biosimilar that we will launch next year.

Kåre Schultz A
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

Thank you for the questions.

Operator: Thank you. And the next question comes from the line of David Amsellem from Piper Sanders (sic) [Piper Sandler]. Please ask your question. Your line is now open.

David Amsellem Q
Analyst, Piper Sandler & Co.

Hey. Thanks. So, I wanted to get some additional thoughts from you, Kåre, regarding business development and M&A and specifically, the extent to which you're prioritizing the addition of brand assets. And to that end, can you talk about your financial wherewithal to do consequential M&A? How large of a transaction can you contemplate both now and also in the context of a global settlement being effectuated? So, I wanted to get your thoughts there. And then as a corollary to that, is it fair to say that you're going to look for neuroscience-focused assets or are you looking at other therapeutic verticals? Thank you.

Kåre Schultz A
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

Thank you for those two questions. I'll answer both of them. So, first of all, of course, it will be nice to do some interesting M&A, but you got to look at our balance sheet, and we don't really have any cash or significant debt capacity on our balance sheet. So, that's not really going to happen in terms of any major transactions for the next several years.

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What you will see us doing, which is what we have been doing is, you could say, early stage in-licensing of interesting assets that we can take through development on our own or together with a partner. And that we will continue to do, of course, but you will not see us doing any major M&A transactions. We simply do not have the balance sheet for that as we speak, and that's with or without an opioid settlement.

You could say M&A based on, you could say, capital – based on share capital is a theoretical option, not with our current ratios, that would be value-destroying for the shareholders. But potentially, in the future, if the share price improves, then of course that is a theoretical opportunity. But cash-based acquisitions, no, that you'll not see in the coming years.

Then in what areas do we want to do these early stage in-licensing. Well, we basically focus on neuroscience and immunology. Those are the two areas where we have the most knowledge, and that's where we have our current portfolio. We have 15 very exciting biopharmaceutical projects right now in the clinic. And those will be there so that we'll be focusing on. And some of the recent deals we've done with early stage assets have also been in those areas. So, we'll continue down that path. Thank you for the questions.

Operator: Thank you. And the next line – or the next question comes from the line of Umer Raffat from Evercore ISI. Please ask your question. Your line is now open.

Eric Musonza
Analyst, Evercore
Q

Hi, this is Eric Musonza speaking for Umer Raffat. Can you hear me? Just wanted to make sure. I've been having audio issues.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.
A

We can hear you.

Eric Musonza
Analyst, Evercore
Q

Great. I just have one quick question on opioids first. Lately, we've been seeing a lot more of the states that opted out of the nationwide settlement, reaching agreements on a state-by-state basis. Are these states requiring more cash per capita compared to those that were in the agreements from your perspective? And just one follow-up.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.
A

So, no, that's not the case. If you look at, you could say, Texas and Florida, then, of course, it's a – all the deals are slightly different, but the key elements are that, of course, we see products in there, we see cash in there, we see a long payment period in there, and that's what we've been saying from the beginning.

If you want to think philosophically about what has changed, then compared to the nationwide settlement where the four other big companies, the three big distributors and J&J, they offered cash only. Back then, we offered basically product only and a little bit of cash. And now we've adjusted it. And of course, it goes hand in hand with the fact that we have the capability now of paying slightly more cash than we could some years ago. We've stabilized the business. And if you sort of look at what we're doing right now with the individual states that we're settling, this is very much in line with what we would hope to do on a nationwide basis.

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Eric Musonza
Analyst, Evercore

Q

Got it. And just a follow-up on the AJOVY and AUSTEDO that we saw in the US. It seems that consensus was expecting a bit more than what was actually reported. Do you think consensus numbers need to rebase, or do you think the US market has drivers that aren't being accounted for?

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

No, I don't think so. I think actually, the consensus numbers for the US are pretty close on a full year basis to our consensus numbers. And we are reconfirming those. It's correct that if you look at the quarters, as I showed you, then we had this big swing always between fourth quarter, first quarter due to the spec buying and the donut hole. And we're also seeing that this year, but we are reconfirming our AUSTEDO outlook of $1 billion. And that is the way I remember it from different consensus as I've seen, that's pretty close to the consensus in the marketplace.

Eric Musonza
Analyst, Evercore

Q

Got it. Thank you.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Thanks for the questions.

Operator: Thank you. And the next question comes from the line of Chris Schott from JPMorgan. Please ask your question. Your line is now open.

Chris Schott
Analyst, JPMorgan Securities LLC

Q

Great. Thanks. Just two for me. I guess, first, on the next set of guidance targets, I know you're going to give that later this year, but it seems like the past five years, we're kind of stabilizing the business, really focused on margin improvement. I guess, high level, as you think about kind of post-2023, does the focus pivot more to top line growth or is it still going to be a very margin-centric story? I'm kind of asking for maybe a bit of a preview of how to think about kind of Teva longer term. And I know we'll get more details later this year, but any color there would be appreciated.

And then the second one for me was on the quarterly revenue progression. You're talking about this kind of 45%-55% split for the year, which I think is a bit more back-end loaded than we typically see. I guess how much of that ramp is tied to products where you have, I guess, full clarity on approval and are more commercial execution related versus how much of that is tied to assets where maybe you're still waiting for approval. I'm trying to get a sense of just the risk tied to FDA or regulatory on getting to that second half ramp. Thanks so much.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Yeah. Thanks for those questions, Chris. So, I'll give it a shot at both of them and then Sven can give some additional color to the last one. So, if you think about what we will be communicating in terms of long-term guidance later sometime in the coming year, then you should really think about it as explaining the same plus

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more, I would say. So, we will not get away from the fact that we need to keep on generating cash and we need to keep on reducing our debt.

I think that's pretty obvious to anybody who is looking at the business. We also want to secure that the business is sustainable. So, as I said before, we also want to give a target for continued margin improvement. But you're also right that, of course, we would also like to see the business returning into a growth mode with increasing revenues. So, I think you should expect, you could say, more of the same with an addition would be the way I would phrase it by now. And then, of course, I look forward to communicating the specifics.

On the revenue side, it's a combination. You could say we knew already when we communicated for the full year that we saw some elements in the US where there were some swing factors between the fourth and the first quarter. So, we communicated that. We also have a number of launches that we knew would happen and that would have a positive effect which are, you could say, date certain.

And then we have, of course, an accumulated effect also of the ongoing progress of AUSTEDO, AJOVY and so on is doing very well, as you've seen in Europe, and we see very nice script numbers on AUSTEDO. And then, of course, we also have some launches in the US, where we don't have the actual approval yet.

So, maybe, Sven, you can comment on some of the most exciting things that will happen in the rest of the year in the US.

Sven Dethlefs
Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.
A

Yes. Thank you, Kåre. So, for AJOVY, we expect a steady development that is based on improved market access and improved market share. For AUSTEDO, we see a pretty good development now with our TV campaign and the patient activation in script count we had within the quarter from January to March, a significant step-up in TRx-es. So, we expect AUSTEDO to grow throughout this year towards its guidance target.

In generics, of course, we had in the first quarter now a significant step-down in TRUVADA and Atripla. We also had, as a reminder, last year in Q1, a loading effect for EpiPen because the approval of the COVID vaccine led to an EpiPen spike that we've seen in 2021. So, that didn't repeat in 2022. But for generics, the outlook, of course, is that we are not independent of the macro environment in the US with the price deflation, but we have now launched REVLIMID in March 2022, so just four weeks ago.

And that will continue to build up revenues for us throughout the year within the settlement framework that we have with BMS and then we have a couple of other products where we still expect or hope for approval from the FDA in generics. The most important one for us is [ph] Forteo (36:43) which would be also a significant contributor to our sales in 2022. So, the bottom line is that we expect a gradual development throughout the year and a buildup of revenues towards the end of the year.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.
A

Thank you for the questions.

Operator: Thank you. And the next question comes from the line of Elliot Wilbur from Raymond James. Please ask your question. Your line is now open.

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Elliot Wilbur
Analyst, Raymond James & Associates, Inc.

Q

Thanks. Good morning. Perhaps for Eli, just wanted to ask a question around the operating profit impact from the reduction to your top line guidance owing to currency, specifically, and then thinking about the combined impact of currency assuming that there is one combined with lower expected profit contribution from COPAXONE, which is not insignificant still. Trying to think about what some of the potential offsets to those may be that enabled you to still maintain prior adjusted EBITDA and free cash flow guidance. Or should we be thinking a little bit more along the lines that these numbers may be a little bit more skewed towards the lower end of the range versus where they currently stand?

And then I had a follow-up question for you, Kåre, on the legal settlement provision this quarter. Just want to get a sense of where or what the current balance sheet accrual is for legal settlements and loss contingencies. I'm assuming it's over $3 billion now. And just trying to get a sense based on some of the settlements that have been entered into recently, which seem to be along similar lines of what we've seen really over the last year or so, why we've seen a fairly significant step-up in the accrual related to potential settlements on opioid litigation. Thanks.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Thanks, Elliot. So, Eli will talk first about the currency elements.

Eli Kalif
Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.

A

Yeah. Thanks, Elliot, for the question. So, we still stick to what we said in February in terms of the margin, which mean that according to our long-term financial targets with the baseline of 2019 onwards to top total 350 basis point up to the 28% OP, which is leading us to top this year as well, like 0.7% year-over-year on gross margin. And the flow-through will be going to the OP. Part of those, I will say, elements impacting on revenue.

As you know, we're also operating in those country that actually we are getting kind of less on the expenses. So, it's kind of not offsetting all of this one. I will say, not the full offset. But because of our ongoing activities, mainly on COGS reduction, and we see it quarter over quarter and the fact that we remove certain fixed costs, mainly with manufacturing footprint from our portfolio, and we see now kind of a benefit that already help us to offset those things. So, all in all, if you look on our current midpoint on the new guidance, we should land at the same more or less margin that we topped already in Q1, around 27.5% to 27.7% for the year.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Thank you, Eli. And on the legal provision, then the legal provision for the opioid litigation is now at $2.6 billion, which is an increase of $1.1 billion versus the last quarter. And it's really the result of a holistic assessment of what's the effect of the settlements we've done so far, what's the most likely outcome based on our current negotiations. So, you should see there's a holistic assessment that we do. And of course, there's a lot of detailed factors in there. There's products in there of various volumes, there's cash in there over various periods and so on. So, that's really our best guess as we speak. Thank you for the questions.

Operator: Thank you. And the next question comes from the line of Ronny Gal from Bernstein. Please ask your question. Your line is now open.

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Ronny Gal
Analyst, Sanford C. Bernstein & Co. LLC

Q

Good morning, everybody, and thank you for taking my questions. I'll ask two. The first about the CRL on risperidone, can you just talk a little bit about what the issue is here? Risperidone is a known molecule with known efficacy to the formulation, is it lack of manufacturing? Is it lack of preclinical data, where are the gaps?

And the second one about the material contribution from adalimumab in 2023. Is it something you're going to see? Or is it more of a 2024 contribution?

And probably my last call, my questions, I want to sneak one in. Eli, if you can tell us what this $2.6 billion in provision for the opioid settlements mean in terms of undiscounted dollars, essentially, there's some discounting assumption thrown in there about how long it will take to pay. But how much is kind of like the non-discounted dollar value it represents?

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Thank you for those three questions, Ronny, and good luck in your future career. So, the first one, the CRL, I can't tell you all the details but I can tell you it has nothing to do with, you could say, efficacy and safety. We have very, very good efficacy data, very good safety data. We are very confident that the principle works very, very well. But it's to do with some details around how, you could say, the whole execution of the clinical trials have been done and some details there, which we are confident that we can address and correct and communicate back to FDA within a maximum six months. And then we expect a review time of six months. So, we still have high trust in the fact that we can get the product approved at the end of the day.

Then on HUMIRA, Sven, will you handle that question?

Sven Dethlefs
Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.

A

Yes. Thank you, Kåre, and congratulations Ronny to your new job. So, the question was if adalimumab biosimilar becomes a material event for us in 2023 or 2024. I believe this is dependent on the market access strategy of payers, how they think about the switchover between AbbVie to the biosimilar offering. And that can happen in the summer of 2023 given that there are many now available options or it is pushed out to 2024 depending on the contracting strategy of the payers.

So, of course, we are committed to come to market in 2023 in the summer and also to have a broad offering. But I believe payers will look in a couple of factors to come up with their strategy. Of course, one is the product feature, then the reliability of suppliers of all the companies coming to market because that is a significant volume market in the US. And of course, AbbVie is able to cover 100% of the volume, then it will be driven by, of course, attractive prices. And then, as I said, the experience to create a pull-through in the market itself once you have contracted.

And I think these four factors will define the market access strategy overall. And once we have the contracting rights, at that moment, only at that moment we can say whether it is a material event for us in 2023 or then in 2024. But it will for sure be one in 2024.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

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Yeah. So, thanks for that answer, Sven. And of course, Ronny, I would say, I would be disappointed if it's not a material event in 2023 because, of course, we are aiming at launching for the settlement date. And we are happy, of course, that the Alvotech product is already being sold in Europe, so it's in the marketplace. So, we have, you could say, high confidence that that will work out.

On the last question to Eli, just inspiration for you, the settlements we've done, as you've seen, had basically nearly all of them been something like 13 or 15 years payment. But, Eli, you can comment a bit more on the technical details.

Eli Kalif
Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.
A

Yeah. So, Ronny, you can understand that it's a very, I will say, detailed detail, because there are certain layers on what we already settled and the rest of the things. But all in all, it's an average between 13 to 15 years. We're using our company WAC, and this one is kind of a discounting. But we need to understand that most of the discounting related to the cash and because of those layers that we already settled, a part of them already happening in the first years and part of the one that we didn't settle for longer years. So, it's really depend, it's not really a pure linear. And also, we need to understand that embedded there, part of the fees and as well part of the element of the product. But all in all, it's like between 13 to 15 years discounted, the net of $2.6 billion.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.
A

Okay. Thank you for the questions.

Operator: Thank you. And the next question comes from the line of Gary Nachman from BMO Capital Markets. Please ask your question. Your line is now open.

Gary Nachman
Analyst, BMO Capital Markets Corp.
Q

Hi, good morning. First, Kåre, when you think of the operating margin expanding beyond 28% over time, where will that mostly come from, higher-margin products, greater manufacturing efficiencies, lower spend in certain areas? Just qualitatively, how you're thinking about that. And how much higher that could potentially go, could it get into the 30s in a few years?

And then with AUSTEDO, just talk a bit more about how you're confident you could get to the full year guidance of $1 billion. Where will most of the acceleration come from? It does seem like it will be challenging at this point. Thanks.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.
A

Thanks for those two questions. I'll answer the first one and Sven will take the second one. So, the operating margin expansion will primarily come from a combination of gross margin improvement and, you could say, product portfolio improvement, but it's really a basic product portfolio improvement. So, it's also improving the manufacturing cost of product families by consolidation. So, it's not that we're expecting a major shift, let's say, from generics to specialty. It's more the fact that we can, within all the product groups we have, keep on optimizing.

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And that goes for the manufacturing footprint. As you know, last couple of years – last four years, we moved from 80 manufacturing sites down to 50. Right now, we are in the process of moving down another 10 sites to around 40 manufacturing sites. And we'll keep on optimizing and we'll also keep on optimizing our product portfolios. So, all in all, the majority of the benefit will come from gross margin improvements, and there will be limited improvements on, you could say, the commercial cost structure because that's relatively lean by now. And we don't see the same magnitude of improvements.

If you then speculate how much improvement can you see, then it's my experience that when you haven't reached sort of the world-class situation on your manufacturing, then you can do something like 50 to 100 basis points per annum. And we will get back to you with some more firm targets in the coming year on what our long-term financial target for the operating margin will be.

On the AUSTEDO, maybe, Sven, you can give some details on how we see AUSTEDO developing and why we are confident that we can meet the $1 billion sales guidance.

Sven Dethlefs
Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.

A

Yes. Our guidance implies that we have a growth in sales of roundabout 30% versus 2021. Our script count went up quarter-over-quarter by 27%. Also, when you harmonize over two quarters the sales to eliminate the effect of the spec buying and the donut hole in Q1 and Q4 of last year, we also see that the sales are absolutely on track with roundabout plus 32% over these two quarters. And for that reason, I'm quite confident that we can get to $1 billion sales with AUSTEDO in North America.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

And maybe we should just add in the sort of known facts that, of course, one of the key things driving increased scripts and volume for AUSTEDO is tardive dyskinesia. There are only two products approved for tardive dyskinesia in United States. AUSTEDO is one of them. And right now, we are estimating that significantly less than 10% of the population or the patient population suffering from tardive dyskinesia are getting therapy. So, there's a huge unmet potential among the 500,000 people suffering from tardive dyskinesia in United States. So, there's a huge unmet medical need there, which we will be more than happy to, of course, satisfy. Thank you for the questions.

Gary Nachman
Analyst, BMO Capital Markets Corp.

Q

Thank you.

Operator: Thank you. And then last question comes from the line of Jason Burberry (sic) [Jason Gerberry] from Bank of America. Please ask your question. Your line is now open.

Q

Hey, guys. Thanks for taking my question. This is [ph] Bhavna Patel (50:40) on for Jason Gerberry. So, my first question is on US HUMIRA. We're hearing a number of players increasingly talk about the importance of supply commitments in a market like this. Could you talk about your strategy and the percent of the market a supplier

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needs to commit to providing the biosimilar to? And then on generic REVLIMID, could you speak to the extent that Teva could have preferential volume position versus other generics in 2023 or beyond?

And then finally, if I could fit one last in. I'm just wondering if you could provide some insight as to why AUSTEDO sales are so volatile quarter to quarter. It looks like $154 million last quarter versus $282 million this quarter. Is it driven by the stocking patterns or phasing on patient assistance program impact? Thank you.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Thank you for those three questions. I think that Sven will do the majority of the answers here. I'll just say that, in general, when you talk about biosimilar products or for that matter, competing biologics, then, of course, it's always important to have some firm commitments on supplies.

And if we look at what we have been competing recently with the biosimilar to RITUXAN with our TRUXIMA, then we have been targeting from the beginning that we would have double-digit volume share. And right now, we have around a quarter of the market. And that's really what we've been going for. And you can see some patterns, of course, in what's realistic to get when you have a multiplayer competitive situation. And from that, you can sort of deduct a range of volumes that you need.

But I will leave that question and the other two questions for you, Sven, to answer.

Sven Dethlefs
Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.

A

Yes. The first one was on the supply commitment, supply chain question regarding HUMIRA biosimilar. So, our partner is here Alvotech from Iceland. They do the drug substance manufacturing and also the drug product manufacturing, and we are the commercial partner in the US. This is how it is set up. HUMIRA from Alvotech is already approved in the European Union, and it will be launched before we come here to the US market. That gives us some confidence that the supply chain reliability should be there and that we have a good understanding about how much volume we can supply to the US market. There's, of course, also a plan about how volume will be ramped up over time for this product. So, we have clarity in that aspect as well.

And then the volume commitment that we can do in here for the US is dependent on our market access and contracting strategy. So, that will be something that we will balance for the product launch next year, but we are quite confident that we will be in shape for this product launch.

So, the other question was on the AUSTEDO sales volatility. We talked about that before. Of course, we had the spec buying effect in Q4 of last year, and then you always have an inventory, let's say, a reduction on the wholesaling channel in Q1 this year. We've seen this every year. In addition, there is the donut hole effect that comes in, in January, February of this year, and that leads to the sales volatility of AUSTEDO.

Overall, as I said before, the script count is on track and is actually growing very gradually, according to our plans. So, for that reason, we are confident that we'll reach our sales target. And I think there was a third question, but I don't recall...

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Yeah, there was REVLIMID where we have a volume-based settlement.

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Sven Dethlefs
Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.

A

Yes.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

And you can correct me if I'm wrong, Sven, but the way I remember it, there's a volume limitation this year, but also in 2023 and 2024. And then in 2025, that's no longer the case. And there will also be other competitors, which from what I know, also have some kind of volume restriction. So, we'll probably see all-out competition in 2025, and we'll see some, you could say, volume limitations for us in 2023 and 2024.

Sven Dethlefs
Executive Vice President-North America Commercial, Teva Pharmaceutical Industries Ltd.

A

Yes, that's correct.

Q

Thank you.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

So, thank you for those questions.

Operator: Thank you. That does conclude our question-and-answer session. Please continue with your closing remarks.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

Thank you, everyone, for listening in. It was a pleasure, and we'll see you next quarter. Bye-bye.

Operator: Thank you. That does conclude our conference call for today. Thank you for participating. You may now all disconnect.

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